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March 22, 1971

Senator Edward M. Kennedy Chairman, Health Subcommittee Committee on Labor and Public Welfare Washington, D. C. 20510

Dear Senator Kennedy:

I have reviewed with great interest the testimony presented before your Subcommittee on March 9, 1971, in connection with your consideration of S. 34, the "Conquest of <u>Cancer Act</u>," introduced by you and Senator Javits and cosponsored by a number of your colleagues. I am pleased to provide you in this letter my comments on that testimony. I am also enclosing a copy of the statements made by members of our Panel on March 10, much of which is responsive to the testimony presented on March 9.

First, with respect to the statement of Dr. Egeberg, Assistant Secretary, H.E.W., as read by Dr. Jesse Steinfeld, Surgeon General, I am pleased to note the very substantial areas of agreement between that statement and the findings and recommendations of our Report. The bulk of Dr. Egeberg's statement follows precisely the lines of our Report, and I have no differences with those portions of his statement. However, on the question of how the job can best be done, there are very important differences between our recommendations and the views expressed in Dr. Egeberg's statement. We recommend the creation of a National Cancer Authority, while Dr. Egeberg urges that the effort remain within N.I.H. and H.E.W. In arguing against the independent agency, it seems to me that Dr. Egeberg lost sight of the real thrust of our recommendations. We were talking about management, and management only. We were not talking about isolating the cancer effort from other aspects of biomedical activities. On the contrary, we would expect the closest cooperation and coordination in this respect. Dr. Egeberg's statement speaks of the new authority "replicating management resources for its own programs at some location distant from the National Institutes of Health," and suggests "that very high costs would be involved, as well as time delays." We have absolutely no thought of moving the National Cancer Institute physically or of terminating or curtailing its efforts while another organization gets started. The N.C.I. would go right along as it is

today, becoming the nucleus of the National Cancer Authority. We are talking only of the simplification and clarification of the management of the cancer effort.

We believe that the effective conduct of the cancer effort requires clearly defined authority and responsibility, and that there should be an independence in management, planning, budget presentation and assessment of progress that does not exist under the present setup. Dr. Egeberg speaks favorably of the management capability and efficiency of the National Cancer Institute, but that is not primarily where the management problems exist today. The primary source of the delays, inefficiencies, competition for funds, and dilution of the cancer priority are not within the N.C.I., but are within the layers of decision-making authority over N.C.I. within the N.I.H. and H.E.W. It is here that we find the six tiers of bureaucracy with multiple decision makers and influences at every level that blur the definition of authority and responsibility, and that preclude the independence in management, planning, budget presentation and assessment of progress that is required. If you assume that the director of the National Cancer Institute was given full authority and responsibility for the cancer effort and was told that he was responsible for management, planning, budget presentation and assessment of progress, and if you assume further that there was created a National Cancer Advisory Board with the powers and functions outlined in our recommendations, and if the director of the N.C.I. then proceeded to implement the recommendations of our Report, this gives you the picture of how the National Cancer Authority would actually work in practice.

This would not move the National Cancer Institute physically; it would not fragment or isolate the cancer effort from other biomedical sciences; it would not minimize basic research or diminish the emphasis on grants; it would not in any way threaten the basic scientists or the support of medical schools, but it would provide clearly defined authority and responsibility; it would provide independence in management, planning, budget presentation and assessment of progress; it would provide participation in the planning effort by the scientists who will be primarily involved in the execution of the effort; it would provide the mechanics for peer

review without the inefficiencies and delays that exist today; and it would assure that the cancer effort retained whatever priority the Congress assigned to it and that the funds provided for the cancer effort were not used for the support of other purposes, however meritorious, such as unrelated biomedical research in other fields and medical education.

I would like to emphasize that our Panel is strongly of the view that the cancer effort should not be funded at the expense of other biomedical research or medical education. But the way to avoid this is not to divert funds appropriated to cancer to these purposes, but to use the cancer funds for cancer and look squarely at the funding needs of these other areas.

When I speak of using cancer funds for the cancer effort, I would like to make it clear that I am not talking about a limited programmatic or systems approach. Using cancer funds for the cancer effort would include large segments of basic biomedical research which are relevant or possibly relevant to cancer, but a qualified advisory board which includes eminent basic scientists can draw that line wisely and not narrowly, and it is not essential to the protection of basic science or medical education that the boundaries of the cancer effort be drawn by those whose primary interest is in areas other than cancer.

Dr. Egeberg expresses the fear that a cancer priority "outside the context of requirements for other biomedical research activities and for health as a whole ... ignores not only the question of what constitutes a balanced and reasonable coordinated approach to problems of health, but also the question of competing needs for resources." I believe this is really the crux of the argument for keeping the program in N.I.H. As long as the program is in N.I.H., if cancer receives a disproportionate part of the funds, ways can be found to "balance the program." This seems to me to be the wrong approach. Appropriations for cancer should be used for cancer, and if this slights other basic research or medical education or other health fields, H.E.W., N.I.H., and the Congress should face up to that fact and do what is necessary for these other fields. I certainly would not want to see these other areas slighted, but I think they can get better support on their own merits than through the supposed benefits of having a common budget with the cancer effort.

Finally, Dr. Egeberg makes the argument commonly made that the cancer effort is not scientifically comparable to the space effort or the splitting of the atom. This is, of course, correct. Our Panel was well aware of this distinction and took it into full account. The analogy we were drawing was not the scientific analogy, but the organizational analogy. The cancer program, in order to succeed, needs the same independence in management, planning, budget presentation and the assessment of progress that those programs needed, and in those respects the independent authority analogy is a valid one.

Following the presentation of the prepared statement, the Chairman asked Dr. Baker whether there is a comprehensive, overall cancer program today. Dr. Baker referred to several managed programs within the N.C.I. Our Panel is, of course, familiar with those programs, and we concur with the view that those are sound programs that have been well managed. However, there is no comprehensive overall program plan today, and such a plan is a sine qua non of an effective assault on cancer. Dr. Baker was emphatic about this in his own presentations to our Committee. However, for an overall program plan to be formulated or executed, there is need for the type of independence advocated in the Report, supported by the scientific participation that would be afforded through the National Cancer Advisory Board or some similar mechanism. In the light of the testimony given by the departmental witnesses in answer to questions, I would like to emphasize again that our Panel has not the slightest notion of eliminating the cooperation, coordination, cross-fertilization and interchange between the cancer effort and other Institutes of This cooperation is essential, just as is the cooperation between the federally sponsored effort and the private efforts which are going on throughout the nation. However, under a clearer definition of authority and responsibility and with greater independence of management, this cooperation should be improved rather than retarded.

In the questioning of the witnesses, it was pointed out by Senator Dominick and others that many leads and possibly important answers in the cancer field may come from medical research in areas other than cancer. This is entirely true, was fully recognized by our Panel, and there is no question of the importance which research aimed at cancer has in other fields and research aimed in other

directions has in the cancer field. However, there is absolutely no reason why more efficient or more independent management of the cancer effort would cut off this intercourse between the different research areas. This would, of course, continue and with the improved communications that we recommended and envisaged, and which we believe independence in management will facilitate, this intercourse should be vastly improved.

Repeatedly in the testimony on March 9th there was talk about "keeping the program within the entire scope of biomedical research and taking advantage of all new ideas and new concepts rather than pursuing a single program on a single tract." May I repeat again that there is not the slightest support in any aspect of our recommendations for pursuing a single program along a single tract. We are taking an even wider approach, recommending greater use of broadly based biomedical research and a greater use of new ideas and new concepts. We are only advocating the more efficient management of a better and more broadly defined overall plan.

There was a good bit of dialogue initiated by Senator Pell on the question of whether there exists today adequate data processing facilities for current communication between the various researchers interested in a particular aspect of the cancer field. The answer to that question is "no." We believe that there should be such facilities and we strongly recommend that such facilities be developed, and here again we believe that the effective development of such facilities is much more likely under independent management. discussion before the Committee was somewhat confused by reference to Medlars, a computerized system maintained by the National Library of Medicine, wherein an attempt is made to put all published medical information on tape and make it available from a data bank. However, this system is not programmed specifically to cancer and it stores only published information. Although this is useful, we believe that there is an urgent need for a central data bank where current research information and other information can be stored and exchanged.

I was pleased to hear Dr. Egeberg say "that the Secretary feels that within the N.I.H. he can, with the proper people and with the proper group surrounding those people, create in effect an authority that would focus on this in a quicker way than one can do at the

present time." This is precisely what our recommendations are designed to achieve. For example, if one could visualize the National Cancer Institute being set up with the same clearly defined authority and responsibility, with the same independence of management, with the same type of cancer advisory board, and with the same powers and missions as are set forth in our recommendations, this would in effect provide the results we are seeking. However, this will not be true as long as N.I.H. is over the National Cancer Institute, H.E.W. is over N.I.H., they operate under a common budget, and decisions are made as they are today.

Dr. Cooper spoke on behalf of the Association of the American Medical Colleges and expressed apprehension lest the creation of a separate cancer authority might begin the destruction of the National Institutes of Health and thus eliminate this source of support for medical education. We see no reason for believing that the creation of a National Cancer Authority would destroy or even weaken the National Institutes of Health. This would be true only if the Congress acted in such a way as to produce that result, and I have seen no evidence that the Congress is likely to take such action. We are not only in favor of a continued strong N.I.H., but we also favor a strengthening of the support of medical education. An independent cancer authority would undoubtedly support basic and other research relevant to cancer conducted by medical schools and hospitals associated with medical schools at a higher rate of support than is the case today. Moreover, no part of the cancer program is intended or should have the result of reducing other support for medical schools. However, support of medical schools from funds appropriated for cancer research should be based upon the merits of the proposed research. Under this criteria. I would see no threat to the medical schools from the recommendations of our Panel.

Several of the scientific and professional members of our Panel are from leading medical colleges and I think that they understand clearly the thrust and implications of our Report and see therein no threat to the medical colleges. My personal view is that the threat that is seen in our Report to the medical colleges comes from a misunderstanding of our recommendations. I think here again the worry is that cancer will get a higher priority in funding than other equally meritorious causes such as the support of medical education.

Dr. Schneider spoke on behalf of the American Societies for Experimental Biology. His remarks indicated a worry that the recommendations of the Panel would lead to a reduction in the support of basic biomedical research or a reduction in the independence of the researchers. I believe a thorough reading of our recommendations makes it clear that precisely the opposite will flow from the implementation of our recommendations. The support of basic research will be increased. The use of the grants mechanism will be increased, scientists will participate in the formulation of the overall plan as well as the specific plans, and there will be much larger segments of non-programmed basic research than is the case today. I believe the worry here stems from the fact that today this type research derives much of its support from the N.I.H., so that naturally the recipients of that support are uncomfortable with the prospect of a change when they are not certain how that change will affect them. I have no question that they will find that the implementation of our recommendations will affect them favorably. This was the view of the very distinguished basic scientists on our Panel. This view was elaborated in more detail in the testimony of Dr. Kaplan before your Committee.

Dr. Lee pointed out once again that the problem of cancer "represents a complex, multifaceted challenge at least as perplexing as the problem of the various infectious diseases," and therefore "is in no way comparable to a moon shot." As pointed out above, this was clearly understood by the Panel, but it was not thought to militate against striving for a more efficient management of the cancer effort. I have no doubt that those managing the cancer effort under an independent authority would be as fully aware of the complexity of the cancer problem and what is required to solve it as are those who point out this distinction between cancer and other programs. Once again, the analogy we are drawing is not the scientific analogy, but the organizational analogy. Dr. Lee also suggests that independence of management means separation and a loss of intimate interchange of ideas and interaction among investigators. This clearly need not follow. For example, there is as much interchange between investigators at Rockefeller University and others working on similar problems as there would be if Rockefeller University were a formal part of and governed by a larger medical school. There can be efficiency without isolation on program control. Dr. Lee then expresses his concern about competition for scarce resources. Here again, the crux of the criticism is the fear that

an independent cancer authority will enable the cancer effort to drain resources from other medical areas. This would be so only if the Congress makes it so. But, in my view, it is a principal basis of the opposition from those who currently receive support from N.I.H.

Dr. Carl Baker, Director of the National Cancer Institute, and two of his colleagues testified before our Panel, and several hours were spent with Dr. Baker discussing the recommendations of our Report. Following Dr. Baker's appearance before our Panel, I asked him to outline in a memorandum the points covered in his testimony. I would like to quote from that portion of his memorandum dealing with organization. In so doing, I would like to make it clear, as Dr. Baker did, that he was speaking personally from his own experience and was not professing to voice the views of the Department or the Administration. I would also like to make it clear that Dr. Baker's remarks were not the basis of our recommendations. However, they touch in a very important way on many of the factual points which led to our recommendations. Dr. Baker's memorandum reads as follows:

"The managerial needs were briefly outlined which would be necessary if a much larger attack was instituted. Primarily, much more rapid decision making and much more rapid response time after decisions are made would be absolutely necessary. A drastic reduction in the number of people involved in decision making (whether advisory or otherwise) would be required, and great simplification of organizational arrangements would be necessary including particularly a return to a hard pyramidal line command structure. The Director cited the importance of such features as seen from his review of a number of major technical successes of mankind of large scale such as the air defense in the Battle of Britain, the Manhattan Project, and the moon shot.... Moreover, the cost of review time and delay spent on reviewing small packages of research efforts would preclude much greater expansion if program size were considerably enlarged, to say nothing of questionable efficiency of such use of senior talent on relatively small matters. Lastly, the difficulties of sound program management when budgets are not known until the fiscal year is

nearly gone do not require much elaboration. The need for no year money or five year money or even three year money might be helpful in this regard, as would budget review cycles based on something other than our present fiscal year constraints. The time required currently for approvals of certain appointments and promotions, for construction and renovation clearances, and for other so called "staff" functions would require changing if a major, larger attack is to be successfully launched."

I believe that the views expressed by Dr. Baker to our Panel give a better picture of the nature of the problems than does the testimony of the Department's witnesses before the Subcommittee.

Finally, I would like to make it clear that neither I nor any of the members of our Panel want any political conflict or any conflict with the Administration on a matter that ought so clearly be a nonpartisan or bipartisan question. We all realize that the American people do not want to see the cancer problem become a political or partisan issue. It has been our aim to work as closely with the Administration as with the Congress. Soon after the appointment of our Panel, I sought and received an appointment with Secretary George Shultz at the White House to acquaint him with our Panel and its mission and to assure him of our desire to work closely with the Administration. Dr. Farber, Dr. Clark and I met with Secretary Richardson and members of his staff to discuss our recommendations soon after they were presented to the Senate. Dr. Kaplan and I met with Dr. David and the President's Scientific Advisors and discussed the Report for two hours. The staff of our Committee was housed at the National Cancer Institute and we worked most closely with the N.C.I. on the development of the facts on which our recommendations were based. There is no desire to dismember or weaken in any way the N.I.H. Our only interest is in seeing the cancer effort succeed. I agree with everything in Dr. David's recent address on this subject except his conclusion that the cancer program can best be carried out within the N.I.H.

Whatever the outcome of the organizational discussions, I hope you will insist upon a clear definition of authority and

Senator Edward M. Kennedy -10.

responsibility and the independence in management, planning, budget presentation and assessment of progress which a complex scientific program of this sort requires. Without these attributes, the chances for the Conquest of Cancer hold considerably less hope.

With deep appreciation for the courtesies shown to me and the members of our Committee, and for your cooperation in this subject which so vitally affects so many of our citizens, I am,

Sincerely yours,

Benno C. Schmidt

Attachment